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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,988	09/15/2001	Donald W. Hansen JR.	3366/1 US	7678

7590 03/27/2002
Pharmacia Corporation
Corporate Patent Department
800 N. Lindbergh Blvd.
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St. Louis, MO 63167

EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 03/27/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,988

Applicant(s)

HANSEN ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20²⁰² is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 202 is/are allowed.
- 6) ☒ Claim(s) 1-201 and 203 is/are rejected.
- 7) ☒ Claim(s) 204 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
2. The disclosure is objected to because of the following informalities: Page 44, line 19 colon should be at end of line above. Appropriate correction is required.

Claim Objections

3. Claim 204 is objected under 37 CFR 1.75 to as being a substantial duplicate of Claim 202. Claim 204 simply recites the chemical names of the compounds whose structures are given in claim 202. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the limitation "R3 is C1-C5 alkyl" in line 2 while the claim on which it depends requires fluorine substitution. There is insufficient antecedent basis for this limitation in the claims.

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5. Claims 131 and 132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the limitation "R3 is" "C1-C5 alkyl" and "methoxy methyl" in line 2 while claim 126 on which they depend requires fluorine substitution. There is insufficient antecedent basis for this limitation in the claims.
6. Claim 134 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the limitation "R3 is methyl" in line 2 while claim 126 on which it depends requires fluorine substitution. There is insufficient antecedent basis for this limitation in the claims.
7. Claims 198-201 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the limitation "R3 is " a group other than halo substituted alkyl in line 2 while claim 193 on which they depend requires fluorine-substituted alkyl. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

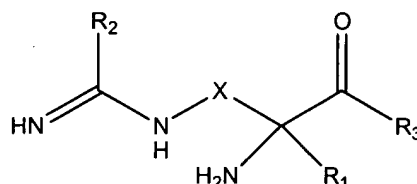
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-12, 19-23, 31-40, 50, 58, 66- 79, 89, 97-107, 114-118, 125,133 –146, 153-156, 164-174, 181-184, 192, 200, 201 and 203 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al (WO 95/25717-A1 10-1995). Currie generically discloses (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I) which embraces the instant compounds:



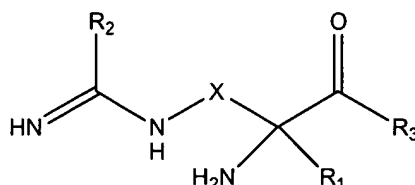
where R₃ may be hydroxyl, R₂ may be methyl and R₁ may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl, lower alkynyl, where "lower" denotes 1-6 carbons. One of ordinary skill in the art could immediately write down all compounds in this preferred subgenus along with all stereoisomeric forms of the chiral center and double bonds. Thus Currie's generic disclosure is anticipatory of the above-enumerated claims notwithstanding the fact that the individual compounds are not named. The instant compound, for example, on page 95, line 27 of the specification in Claim 202 is also thus anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-201 and 203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al (WO 95/25717-A1 10-1995) and further in view of Hallinan et al (US 6,344,483 02-2002). Currie generically discloses (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I):



Where R₃ may be hydroxyl, R₂ may be methyl and R₁ may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl, lower alkynyl, where lower denotes 1-6 carbons. Currie further teaches (Page 7, lines 27-30) alkyl and halo substitution of the alkenyl and alkynyl core.

Hallinan teaches (Column 3, line 24 - column 4, line 48) nitric oxide synthase inhibitors closely related in structure to Currie's and refers (Column 3, line 3) to Currie's disclosure directly. Hallinan further discloses alkenyl (Column 18, line 1 –

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column 19, line 2) and alkynyl (Column 19, line 3- column 20, line 27) amidino amino acids. Hallinan also discloses (Column 26, lines 1-23) the use of fluoro substitution.

Hallinan disclosure and teachings provide the motivation for one of ordinary skill in the art to actually synthesize the alkenyl and alkynyl compounds taught by Currie. –

Thus it would have been obvious for one of ordinary skill in the art to have performed the instant invention at the time applicant asserts it was made. The motivation for combination of the two references is provided by the reference by Hallinan to Currie as well as the common field of invention. The expectation for success would have been near certitude since Currie's genus completely embraces the instant compounds which, Currie teaches, have the instantly desired activity as nitric oxide synthase inhibitors.

Allowable Subject Matter

10. Claims 202 and 204 are drawn to allowable subject matter. The following is a statement of the reasons for indicating allowable subject matter. The closest art of record Beaulieu et al (Journal of Organic Chemistry 1991, 56, pages 4196-4204) teaches (Page 4197, right column, top, Figure 2 and Table I, entries 7 and 8; page 4199, left column, top, Table II) a method of synthesis of cyano-substituted chiral vinyl glycines but neither discloses nor fairly suggests the α -methylated compounds of instant claims 202 and 204.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Applicant is advised that should claims in the left hand column below be found allowable, claims in the right hand column will be objected to under 37 CFR 1.75 as being substantial duplicate(s) thereof:

If these claims found allowable:	these will be objected to:
7-24	35-52
4-6	32-34
3	31
2	30
79-96	107-124
146-149	174-177
151-155	179-183
157-163	185-191
202	204

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper

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after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

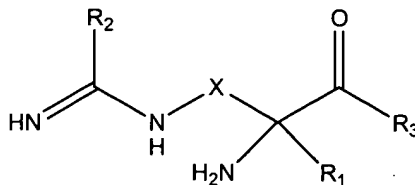
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection.

12. Claims 1-201 and 203 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-202 of copending Application No. 09/952,888 in view of Currie et al (WO 95/25717-A1 10-1995).

Currie generically discloses (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I):



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Where R_3 may be hydroxyl, R_2 may be methyl and R_1 may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl, lower alkynyl, where lower denotes 1-6 carbons. Currie further teaches (Page 7, lines 27-30) alkyl and halo substitution of the alkenyl and alkynyl core.

Instant claims 1-201 and 203 are drawn to compounds that differ in structure from those claims 1-202 of copending Application No. 09/952,888 only by the fact that a single methylene group has been deleted from the alkyl carbon chain. The instant compounds are thus prima facie obvious over those of 09/952,888 since they would be an expectation by one of ordinary skill in the art that they would have similar utility.

In the instant case this obviousness is reinforced by the common membership in the genus of Currie of the instant compounds and those of 09/952,888.

Conclusion

13. Claims 1-204 are outstanding. Claims 1-201 and 203 are rejected. Claim 202 is allowed. Claim 2024 is objected to.

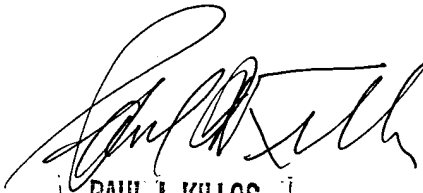
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ
March 22, 2002


PAUL J. KILLOS
PRIMARY EXAMINER
AH-1627